



## **Alseres Receives Special Protocol Assessment Agreement from FDA for Phase III Trial of Altropane**

### **--Agreement opens clear path to NDA for early diagnosis of Parkinsonian Syndromes**

HOPKINTON, Mass., April 6, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Alseres Pharmaceuticals, Inc. (Nasdaq: ALSE) announced today that it has reached agreement with the US Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) process for the Phase III protocol of Alseres' Altropane(R) Molecular Imaging Agent to aid in the early diagnosis of Parkinsonian syndromes including Parkinson's disease. A SPA agreement defines the size, design and analysis of clinical trials that will form the primary basis of approval. The Altropane Phase III program, called POET-2 (Parkinson's or Essential Tremor), is designed to confirm the diagnostic utility of Altropane in anticipation of drug registration, and includes two, parallel clinical studies enrolling up to 480 subjects in total.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20080813/NEW056LOGO> )

"This is excellent news. Agreement with the FDA on the POET-2 protocol is an important step forward for our field," Ray L. Watts, M.D., John N. Whitaker Professor and Chairman of the Department of Neurology, University of Alabama at Birmingham stated. Dr. Watts continued, "A major problem to date is that we have not had an objective test to aid in the differentiation of Parkinson's disease from other tremor disorders such as Essential Tremor. The early and accurate diagnosis of Parkinson's disease with Altropane will allow patients to take advantage of new neuroprotective and disease modifying therapies as they become available."

Following an evaluation of images produced with Altropane during the preliminary stage of the POET-2 program, John Seibyl, M.D., President of Molecular NeuroImaging, LLC, said, "Altropane images were produced on a variety of SPECT cameras using a convenient, robust protocol. The images are clear and readily interpreted. Altropane shows excellent promise as an imaging agent for the early detection of Parkinson's disease."

"This SPA agreement with the FDA is a key accomplishment for Alseres, providing us with a clear, well-defined path to a marketing application for Altropane," Thomas Tulip, PhD, President of Alseres Molecular Imaging, stated.

"Our objectives for our molecular imaging business are clear: complete U.S. development and seek commercialization partnerships, work closely with patient advocacy and professional organizations to foster greater Parkinson's disease awareness; aggressively pursue development and commercialization relationships outside the U.S.; and continue to expand our molecular imaging intellectual property estate. The completion of the first stage of our POET-2 program and this agreement with the FDA markedly reduce our technical and regulatory risk. As a result, we expect expanding interest in all of these ongoing discussions," Tulip said.

#### About Altropane

Altropane is a molecular imaging agent that specifically and selectively binds to the dopamine transporter (DAT) found on dopamine-producing neurons. Loss of these cells is the hallmark of Parkinson's disease. Altropane used in conjunction with Single Photon Emission Computed Tomography (SPECT) imaging could be useful to distinguish Parkinsonian from non-Parkinsonian tremor: Parkinsonian patients would have reduced Altropane binding, due to fewer DAT sites, and thus reduced activity in the SPECT image. The superior pharmacokinetics and imaging characteristics of Altropane suggest that it has the potential to a "best in class" product around the world. It should address a dramatic and growing unmet medical need in an efficient and patient-friendly manner.

#### About Alseres Pharmaceuticals, Inc.

Alseres Pharmaceuticals, Inc. (ALSE) is engaged in the development of diagnostic and therapeutic products primarily for disorders in the central nervous system (CNS). The Company has a robust molecular imaging development program targeting diagnosis of Parkinson's disease and potentially dementia. The Company's lead molecular imaging product candidate is Altropane which is in Phase III clinical trials for the diagnosis of Parkinsonian Syndromes including Parkinson's disease. The Company maintains a world-class intellectual property position in the field of regenerative therapeutics. Cethrin, a recombinant-protein-based drug designed to promote nerve repair after acute spinal cord injury, demonstrated positive interim results in a Phase I/IIa clinical trial. The Company's research and pre-clinical programs include, Inosine for the treatment of spinal cord

injury and stroke, Oncomodulin for the treatment of ocular injury and disease and research programs directed at a number of regenerative therapies including bone repair.

#### About Special Protocol Assessment

The SPA is a process that allows for official FDA evaluation of a Phase III clinical trial whose data will form the primary basis for an efficacy claim and provides trial sponsors with a binding written agreement that the design and analysis of the study are adequate to support a license application submission if the study is performed according to the SPA. The SPA agreement may only be changed by the sponsor or the FDA through a written agreement, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit <http://www.fda.gov/cder/guidance/3764fnl.htm>

#### Forward-Looking Statements

The foregoing release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding Alseres' future expectations, beliefs, intentions, goals, strategies, plans or prospects regarding the future, including the Company's ability to obtain financing, the development and commercialization of Altropane and Cethrin, the prospects of the Company's CNS and regenerative therapeutics programs, the Company's strategies to develop and commercialize axon regeneration technologies and the breadth of the Company's technologies and intellectual property portfolio. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors including those risks, uncertainties and factors referred to in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Alseres from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. Alseres is providing the information in this press release as of this date and assumes no obligations to update the information in this press release.

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